

IN THE CLAIMS

1. (original) A method for the sterilization of a labile glucocorticosteroid, comprising the step of applying a moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time.
2. (original) A method for the sterilization of a glucocorticosteroid, comprising the step of heating an aqueous suspension of a glucocorticosteroid, wherein the glucocorticosteroid has a sufficiently low solubility in water and is used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during heating.
3. (original) The method of claim 2, wherein at least 60% of the glucocorticosteroid is in the form of a suspension during heating.
4. (currently amended) The method of ~~any preceding claim 2~~, wherein said heating is at a temperature of from about 101°C to about 145°C.
5. (currently amended) The method of ~~any preceding claim 2~~, wherein said heating is carried out by autoclaving.
6. (currently amended) The method of ~~any preceding claim 2~~, wherein said heating is carried out for about 2 to about 180 minutes.
7. (currently amended) The method of ~~any preceding claim 2~~, wherein the suspension further comprises a surfactant.
8. (original) The method of claim 7, wherein the surfactant is present at a concentration of from about 0.75mg/ml to about 60mg/ml.
9. (currently amended) The method of ~~any preceding claim 2~~, wherein the glucocorticosteroid is budesonide or beclomethasone dipropionate.

10. (currently amended) The method of claim 9, wherein ~~the said~~ glucocorticosteroid is budesonide, and the heating is carried out at 121°C for about 20-30 minutes or at 110°C for about 120 minutes.

11. (currently amended) The method of claim 9, wherein ~~the said~~ glucocorticosteroid is beclomethasone dipropionate, and the heating carried out at 121°C for about 20-30 minutes or at 110°C for about 120 minutes.

12. (currently amended) The method of ~~any one of claims 2 to 11~~, wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml.

13. (original) A method for the sterilization of budesonide, comprising the step of heating an aqueous suspension of budesonide at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes.

14. (currently amended) The method of ~~any preceding claim 13~~, further comprising the step of diluting the suspension to a pharmaceutically suitable concentration.

15. (currently amended) A composition obtainable by [the method of] ~~any preceding claim~~. (i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml; (ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or (iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes.

16. (currently amended) A sterile aqueous suspension comprising a glucocorticosteroid obtained by [the method of] ~~of any of claims 1 to 14,~~ (i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml; (ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or (iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes, wherein the particle size of the glucocorticosteroid is such that the Dv100 is less than 20 μ m, the Dv90 is less than 10 μ m and the Dv50 is less than 5 μ m.

17. (currently amended) A sterile aqueous budesonide suspension obtained by [the method of] ~~of any of claims 1 to 14,~~ (i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml; (ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or (iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes,—wherein the suspension comprises less than 0.2% by weight of 1,2-dihydro budesonide based on the amount of budesonide.